

§810.16

any envelope in which it is sent or enclosed shall be conspicuously marked, preferably in bold red ink: “URGENT—[DEVICE CEASE DISTRIBUTION AND NOTIFICATION ORDER] or [MANDATORY DEVICE RECALL ORDER].” Telephone calls or other personal contacts may be made in addition to, but not as a substitute for, the verified written communication, and shall be documented in an appropriate manner.

(c) *Contents.* The person named in the order shall ensure that the notice of a cease distribution and notification order or mandatory recall order:

- (1) Is brief and to the point;
- (2) Identifies clearly the device, size, lot number(s), code(s), or serial number(s), and any other pertinent descriptive information to facilitate accurate and immediate identification of the device;
- (3) Explains concisely the serious, adverse health consequences that may occur if use of the device were continued;
- (4) Provides specific instructions on what should be done with the device;
- (5) Provides a ready means for the recipient of the communication to confirm receipt of the communication and to notify the person named in the order of the actions taken in response to the communication. Such means may include, but are not limited to, the return of a postage-paid, self-addressed post card or a toll-free call to the person named in the order; and
- (6) Does not contain irrelevant qualifications, promotional materials, or any other statement that may detract from the message.

(d) *Followup communications.* The person named in the cease distribution and notification order or mandatory recall order shall ensure that followup communications are sent to all who fail to respond to the initial communication.

(e) *Responsibility of the recipient.* Health professionals, device user facilities, and consignees who receive a communication concerning a cease distribution and notification order or a mandatory recall order should immediately follow the instructions set forth in the communication. Where appropriate, these recipients should immediately notify their consignees of

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the order in accordance with paragraphs (b) and (c) of this section.

§810.16 Cease distribution and notification or mandatory recall order status reports.

(a) The person named in a cease distribution and notification order issued under §810.10 or a mandatory recall order issued under §810.13 shall submit periodic status reports to FDA to enable the agency to assess the person's progress in complying with the order. The frequency of such reports and the agency official to whom such reports shall be submitted will be specified in the order.

(b) Unless otherwise specified in the order, each status report shall contain the following information:

- (1) The number and type of health professionals, device user facilities, consignees, or individuals notified about the order and the date and method of notification;
- (2) The number and type of health professionals, device user facilities, consignees, or individuals who have responded to the communication and the quantity of the device on hand at these locations at the time they received the communication;
- (3) The number and type of health professionals, device user facilities, consignees, or individuals who have not responded to the communication;
- (4) The number of devices returned or corrected by each health professional, device user facility, consignee, or individual contacted, and the quantity of products accounted for;
- (5) The number and results of effectiveness checks that have been made; and
- (6) Estimated timeframes for completion of the requirements of the cease distribution and notification order or mandatory recall order.

(c) The person named in the cease distribution and notification order or recall order may discontinue the submission of status reports when the agency terminates the order in accordance with §810.17.